

Mary 21, 1999

12:42

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857-0003

Re: Docket No. 98N-1265

Dear Sirs:

I send this letter as a consumer of healthcare services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

I receive my prescriptions from a compounding pharmacy in Wisconsin and am very happy with this pharmacy. While living in New York, I tried a compounding pharmacy in New York and it was not satisfactory. It did not compare with the Wisconsin pharmacy in quality or customer service, and it was three times the cost. I went back to the Wisconsin pharmacy and have stayed with them even after my move to North Carolina. I think it very unfair to prohibit me from dealing with this pharmacy because I live in another state.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer, there should be no restrictions to the delivery of a compounded medication prescribed for me, regardless of where I may live or may travel. The MOU must be amended!

The FDA is an agency of the U. S. Government that purports to be the "watchdog" for consumer safety. This is not a safety issue!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again the MOU must be amended!

Very truly yours,



Marie Goldenberg

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